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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,540	03/08/2001	Adrian Bot	A30571-A-PCT/USA-A	7183

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EXAMINER	
SGAGIAS, MAGDALENE K	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/801,540	BOT ET AL.	
	Examiner	Art Unit	
	Magdalene K. Sgagias	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 2* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 2* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/03/2003;02/03/2003;02/12/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2 are pending and under consideration. Claim 3 is canceled.

Applicant's arguments filed 04/01/2010 have been fully considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-2 under 35 U.S.C. 103(a) as being unpatentable over Meheus et al, [postgraduate Medical Journal, 63(Supp 2): 139-141, 1987 (IDS)] in view of Whalen et al, (Ann NY Acad Sci, 772:64-76, 1995); Schirmbeck et al, (Journal of Virology, 69(10): 5929-5934, 1995) is withdrawn.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Donnelly et al** (WO 94/21797) in view of **Adkins et al** (J Immunol, 153: 3373-3385, 1994); **Sarzotti et al** (Science, 271, 1726-1728, 1996 (IDS)).

Donnelly et al teaches the production and use of a nucleic acid which, when directly introduced into living vertebrate tissue, induces the production of immune responses which specifically recognize human influenza virus (p 1 lines 10-15). Donnelly et al teaches three types of vaccines are available: whole-virus, subvirion, and purified surface antigen and only the latter two are used in children because of increased febrile responses with the whole-virus

vaccine (p 1, lines 28-31). Donnelly et al, teaches DNA constructs encoding viral proteins of the human influenza virus nucleoprotein (NP), hemagglutinin (HA), neuraminidase (NM), matrix (M), nonstructural (NS), polymerase (PB 1 and PB2= basic polymerases 1 and 2; PA= acidic polymerase) or any of the other influenza genes which encode products which generate specific CTLs (p 8). Donnelly et al discloses a vaccine useful in humans to prevent influenza virus infections (p 23, 27-28 and 76). Donnelly et al teaches that DNA constructs encoding influenza viral proteins elicit protective immune responses in animals (p 23, 27-28 and 76). Donnelly et al teaches immune responses in animals have included antibody and cytotoxic T cell (CTL) generation in mice, and the most striking result of immunization with DNA encoding viral proteins was the ability to confer protection against distinct subtypes of virus. This suggests that adding a CTL-eliciting component to a vaccine should serve to mitigate the impact of new variants which arise in mid-season or are unanticipated when the vaccine strains are chosen each year for the following year. Importantly, immunization with cDNA vectors encoding an HA, NP and MI gene was able to protect more effectively against a drifted strain of virus in ferrets than was the licensed vaccine (p 23, 27-28 and 76).

However, **Donnelly** does not specifically teach immunizing an infant humanl with in the age of birth to one month. However, prior to the time of the claimed invention, **Adkins et al** (J Immunol, 153: 3373-3385, 1994) teach T cells from 4-day-old, naive neonatal mice show diminished Th1-like responses, however, neonatal T cells resembled Th2 cells (or primed adult T cells) in that they produced large amounts of IL-4 (abstract). Adkins suggests that neonatal T cells have a greater requirement for accessory cell signals than do adult T cells and may have important bearing in overcoming neonatal T cell immunodeficiencies in vivo (abstract). Adkins teaches T cells from 4-day-old naive mice resemble primed adult T cells in that they produce large amounts of IL-4 (p3379, 1st column, and 1st paragraph). **Sarzotti et al** (Science, 271,

1726-1728, 1996) teaches induction of protective CTL responses in newborn mice by a murine retrovirus (title). Sarzotti teaches the susceptibility of neonates to virus-induced disease is thought to reflect, in part, the immaturity of their immune systems. However, inoculation of newborn mice with low doses of Cas-Br-M murine leukemia virus induced a protective cytotoxic T lymphocyte (CTL) response (abstract). The inability of neonates to develop a CTL response to high doses of virus was not the result of immunological immaturity but correlated with the induction of a nonprotective type 2 cytokine responses (abstract). Thus, the initial viral dose is critical in the development of protective immunity in newborns (abstract).

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Accordingly, it would have been obvious to the ordinarily skilled artisan to modify the teachings of Donnelly to utilizing DNA vaccine into one month human infants, although Adkins does not per se teach human infants, however, Adkins teaches that T cells from 4-day-old naive mice resemble primed adult T cells in that they produce large amounts of IL-4 (p3379, 1st column, 1st paragraph) and that production of large amounts of IL4 might boost neonatal Th1-like responses where IL-4 produced by neonatal T cells act to downregulate IL-6 production as has been reported for human monocytes (Adkins p 3384, 2nd column, 2nd paragraph) and since induction of protective CTL responses in newborn mice by a murine retrovirus and the inability of neonates to develop a CTL response to high doses of virus was not the result of immunological immaturity but correlated with the induction of a nonprotective type 2 cytokine responses as taught by Sarzotti , with a reasonable expectation of success. One of ordinary skill in art would have been motivated to use one month old infants in order to induced a protective cytotoxic T lymphocyte (CTL) response as taught by Sarzotti and particularly since Sarzotti teaches the inability of neonates to develop a CTL response to high doses of virus was not the result of immunological immaturity but correlated with the induction of a nonprotective type 2 cytokine response thus, the initial viral dose is critical in the development of protective immunity in newborns (abstract).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571)272-3305. The examiner can normally be reached on Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paras Peter can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit 1632

/Anne-Marie Falk/
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